IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IMPAX LABORATORIES, INC.,

Plaintiff,

v.

MEDICIS PHARMACEUTICAL CORP.,

Defendant

/

No. C-08-0253 MMC

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS; VACATING HEARING

Before the Court is defendant Medicis Pharmaceutical Corp.'s motion, filed March 5, 2008, to dismiss plaintiff's complaint for declaratory judgment pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. Plaintiff has filed opposition, to which defendant has replied. Having considered the parties' submissions in support of and in opposition to the motion, the Court hereby VACATES the April 11, 2008 hearing on the matter, and rules as follows.

Defendant is a manufacturer and marketer of drugs, including the brand-name drug "Solodyn," a minocycline extended release tablet used as an oral acne medication, and the assignee of United States Patent No. 5,908,838 ("'838 patent") for the making of such drug. Plaintiff, also a drug manufacturer, has filed, with the Food and Drug Administration ("FDA"), an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug and Cosmetic Act, in order to manufacture and sell the generic version of

Solodyn.

In public statements made in 2007 and 2008, Jonah Shacknai ("Shacknai"), defendant's CEO, as well as other representatives of defendant, addressed defendant's strategy with respect to potential generic competitors to Solodyn. For example, in an "Earnings Conference Call" with investment analysts held on February 28, 2007, Shacknai first stated that defendant would "be very vigorous . . . in enforcing the patents," and then stated: "[W]e have hired a couple of [law] firms that I think are vicious in their enforcement and protection of patents, because we want to send a very strong message that this needs to be an impenetrable defense around this brand." (See Chin Decl. Ex. F at 13.) As a further example, on May 3, 2007, at a health care conference, Shacknai, after noting there had been rumors that "generic companies have eyed this market because of the great success of Solodyn and have either prepared to or actually filed applications [with the FDA]," stated that defendant intended "to enforce with the ultimate vigor the patents that have issued [to defendant]." (See id. Ex. G at 3.)[1]

On January 15, 2008, plaintiff filed its complaint in the instant matter, by which plaintiff seeks a declaration that the claims of the '838 patent are invalid and that plaintiff

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[1] On another occasion, Shacknai stated that defendant "plan[ned] to put relevant parties on notice about potential infringement . . . and the vigorous approach that [defendant] would take to enforcing the patent . . . ." (See id. Ex. H (transcript of May 4, 2007 health care conference).) Additionally, Joe Cooper, defendant's Vice President of Corporate and Product Development, stated that defendant was "aware that there's a lot of noise about the potential for somebody to come into [Solodyn's] market" and stated that defendant would "aggressively prosecute the patents, [and] go after preliminary injunctions to ward off any infringers." (See id. Ex. I (transcript of June 27, 2007 equity conference).) On January 4, 2008, Mark Prygocki, defendants' CFO, stated that Solodyn "is an important brand to [defendant]" and "is something [defendant] spend[s] a lot of time on at the headquarters office and [is] confident that [defendant] can protect." (See id. Ex. L (transcript of Jan. 4, 2008 pharmaceutical conference).)

On two other occasions, specifically, conferences held on November 14, 2007 and February 7, 2008, individuals speaking on defendant's behalf, whose identities plaintiff does not provide, stated that defendant's attempts to protect Solodyn "involved having a very aggressive defensive strategy from a legal point of view," (see id. Ex. K (transcript of Nov. 14, 2007 health care conference)), that defendant has "some of the finest lawyers that are available in the United States," (see id.), and that defendant "[hasn't] been sitting still on the Solodyn franchise" and has "the goal of keeping it alive as long as [defendant] possibly can," (see id. Ex. M (transcript of Feb. 7, 2008 pharmaceutical, biotechnology and medical device conference)).

does not infringe any valid claim of said patent. In the complaint, plaintiff alleges that "generic competitors to Solodyn face the risk of a suit for infringement," (see id. ¶ 10), and that Medicis intends to "aggressively and vigorously enforce the '838 patent against generic competitors," (see id. ¶ 11). Plaintiff alleges that, by letter dated December 20, 2007, it notified defendant that plaintiff had submitted an ANDA,[2] and requested defendant provide plaintiff with a covenant not to sue under the '838 patent. (See id. ¶ 12.) Plaintiff alleges defendant "has not provided the requested covenant not to sue." (See id.)

Defendant asserts it first learned of plaintiff's ANDA submission in January 2008, when it reviewed plaintiff's letter, (see Mot. at 4:13-17); by letter dated January 11, 2008, defendant notified plaintiff that defendant would "consider [the letter] and have a response to [plaintiff] within two weeks," (see Decl. of Jennifer H. Wu in Support of Medicis' Mot. to Dismiss Ex. 2). As noted, plaintiff filed the instant action four days later, on January 15, 2008.

The Declaratory Judgment Act ("DJA"), 28 U.S.C. § 2201, et seq., provides: "In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The "actual controversy" requirement "is rooted in Article III of the Constitution, which provides for federal jurisdiction over only 'cases and controversies.'" See SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1378 (Fed. Cir. 2007). Thus, jurisdiction under the DJA "extends only to matters that are Article III cases or controversies." See id.

"An Article III controversy is found where a plaintiff has demonstrated an injury-in-fact caused by the defendant that can be redressed by the court." Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330, 1340 (Fed.

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[2] The record does not reflect the specific date on which plaintiff submitted the subject ANDA; it would appear, however, that such submission occurred in December 2007, shortly before plaintiff requested defendant provide plaintiff with a covenant not to sue.

Cir. 2007). In determining whether a plaintiff's pleading is sufficient for purposes of the DJA, courts consider "whether the facts alleged, under all of the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." See MedImmune, Inc. v. Genentech, Inc., 127 S.Ct. 764, 771 (2007).

Here, defendant contends plaintiff has not adequately alleged injury-in-fact. In response, plaintiff, citing 35 U.S.C. § 271(e)(2), first argues the filing of an ANDA is sufficient to create an actual controversy for purposes of the DJA. Section 271(e)(2) provides: "It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration fo such patent."

Contrary to plaintiff's argument, an "act of infringement" under § 271(e)(2), is not, by itself, sufficient to create an "actual controversy" for purposes of standing for declaratory judgment relief. Rather, in the cases upon which plaintiff relies, the defendant, in addition to having knowledge of the plaintiff's submission of an ANDA, had taken some affirmative action sufficient to constitute a threat of "imminent injury." See, e.g., Novartis, 482 F.3d at 1341-46 (finding, where defendant had filed suit with respect to one of five patents implicated by ANDA filing, declaratory judgment jurisdiction was proper with respect to remaining four patents); Teva Pharamaceuticals USA, Inc. v. Abbott Laboratories, 301 F.Supp.2d 819, 821 (N.D. Ill. 2004) (finding jurisdiction where, on three prior occasions, defendant had sued plaintiff and/or its affiliate for infringement relating to other drugs for which plaintiff had filed ANDAs); see also SanDisk Corp., 480 F.3d at 1380-81 (noting declaratory judgment jurisdiction generally requires "some affirmative act by the patentee"); Capo, Inc. v. Dioptics Medical Products, Inc., 387 F.3d 1352, 1355 (Fed. Cir. 2004) (holding court's jurisdiction under DJA requires more "than knowledge of or notice of an adversely

held patent").[3]

Plaintiff next contends that defendant's public statements regarding enforcement of it's patent, when coupled with plaintiff's filing of an ANDA, suffice to demonstrate an actual controversy. Again, the cases on which plaintiff relies are distinguishable. See, e.g., Micron Technology, Inc. v. Mosaid Technologies, Inc., — F.3d —, 2008 WL 540182 (Fed. Cir. 2008) (holding "substantial controversy" existed where defendant, in addition to making public statements regarding intent to pursue aggressive licensing strategy, sent four warning letters to plaintiff, and had sued three other manufacturers of same allegedly infringing technology); Adenta GMBH v. Orthoarm, Inc., 501 F.3d 1364, 1370 (holding actual controversy presented where patent assignee told licensee it would "pursue its available legal remedies" if licensee stopped paying royalties, licensee in fact stopped paying royalties, and patentee had previously sued assignee for infringement of same patent); see also Bridgelux, Inc. v. Cree, Inc., 2007 WL 2022024 at *9 (N.D. Cal. 2007) (characterizing as "unremarkable" defendant's public statements at industry meetings that defendant would defend its patents; finding such statements insufficient "to warrant a conclusion that defendants had inflicted 'actual and imminent injury' on plaintiff").[4]

Finally, relying on Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc., 242 F.Supp.2d 311 (S.D. N.Y. 2003), plaintiff argues defendant's failure to provide a covenant not to sue in the 26 days between the mailing of plaintiff's letter seeking such covenant and the filing of the instant action[5] constitutes an additional circumstance sufficient to provide

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[3] Plaintiff's citation to Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997), likewise is unavailing, as jurisdiction was not an issue raised therein.

[4] Plaintiff, noting plaintiff is the "only . . . known generic competitor" to Solodyn, (see Pl.'s Opp'n at 9:19-10:2), argues defendant's public statements regarding enforcement of the '838 patent should not be treated as general statements, but rather as statements directed at plaintiff in particular. The majority of the statements on which plaintiff relies, however, precede plaintiff's informing defendant, in December 2007, of plaintiff's submission of the ANDA. In any event, plaintiff provides no authority holding public statements, no matter how pointed, are, under the circumstances presented herein, sufficient to denote a substantial controversy.

[5] As noted, defendant states it did not review the letter until January 2008.

jurisdiction. Again, the Court disagrees. First, as distinguished from the facts presented in Kos, there was no "refusal," see id. at 317, to provide a covenant. Instead, defendant notified plaintiff it would "consider" the request and respond within a short period of time, (see Wu Decl. Ex. 2), and plaintiff, rather than waiting for defendant's response, chose to file the instant action. Moreover, in Kos, unlike the instant action, the patentee had previously "demonstrated its readiness and inclination to sue" the ANDA applicant by filing three actions against it, all involving patents "substantially similar" to the patent at issue in the declaratory judgment action. See Kos, 242 F.Supp.2d at 315; see also Prasco, LLC v. Medicis Pharmaceutical Corp., 2007 WL 1974951 at *3 (S.D. Ohio 2007) (holding defendant's refusal to provide plaintiff with covenant not to sue, along with defendant's "marking" of products with patents-in-suit and defendant's previous infringement action brought against same plaintiff, not sufficient to establish actual controversy). In sum, taking into account "all of the circumstances" presented, plaintiff has not shown a controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." See MedImmune, 127 S.Ct. at 771.

Lastly, even if plaintiff's showing were sufficient to give rise to standing, the Court would, under the circumstances presented, use its "substantial discretion in deciding whether to declare the rights of litigants," MedImmune, 127 S.Ct. at 777 (internal quotation and citation omitted), to decline to exercise jurisdiction over the instant action. In particular, plaintiff's allegation of jurisdiction rests on the existence of the '838 patent, plaintiff's filing an ANDA, and defendant's failure to immediately agree to a covenant not to sue. If, under such circumstances, the Court were to exercise declaratory judgment jurisdiction, it would promote the premature filing of declaratory judgment actions and reduce the incentive for potential infringers to communicate with patentees before filing suit. See, e.g., Fresenius USA, Inc. v. Transonic Systems, Inc., 207 F. Supp. 2d 1009, 1012-13 (N.D. Cal. 2001) (finding no jurisdiction and, alternatively, declining to exercise discretionary jurisdiction where, at time suit initiated, patentee had sent one letter to plaintiff asserting plaintiff's device infringed; noting exercise of jurisdiction "would create a strong disincentive for

patentees to communicate with potential infringers before filing suit").

Accordingly, for the reasons stated, defendant's motion to dismiss is hereby GRANTED.

IT IS SO ORDERED.

Dated: April 16, 2008

MAXINE M. CHESNEY
United States District Judge